IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of KENNETH E. KADZIAUSKAS ET AL.	Group Art Unit: 3763
Title: CONTROL OF PULSE DUTY CYCLE BASED UPON FOOTSWITCH DISPLACEMENT	Examiner: Paul B. Smith
Serial No.: 10/680,595	Confirmation No. 5761
Filed: October 6, 2003	

AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Official Action dated April 18, 2006, please amend the present application as follows:

Amendments to the Specification are set forth on page 2.

Amendments to the Claims are set forth in the Listing of Claims which begins on page 3 of this paper.

Remarks begin on page 6 of this paper.

AMENDMENTS TO THE SPECIFICATION

Please replace paragraph [0087] as published with the following paragraph:

[0087] Therefore, the positive reference input 96 to the A/D converter 110 is a voltage that is inversely proportional to the frequency of operation. The phase voltage signal 96 is proportional to the phase difference between the leading edge of the voltage onset, and the trailing edge of the current onset, as well as inversely proportional to the frequency of operation. In this configuration, the two ~~signals Frequency voltage reference 96 and phase voltage 46~~ signals, frequency voltage reference 96 and phase voltage 46, track each other over the range of frequencies, so that the output of the A/D converter 110 produces the phase independent of the frequency of operation.

AMENDMENTS TO THE CLAIMS

The following listing of claims replaces all prior versions and listings of claims in this application. In the changes made to the claims by the current amendment, ~~deletions are shown by strikethrough~~, and additions are underlined.

LISTING OF CLAIMS

1. **(Previously Presented)** An ophthalmic lens extraction apparatus comprising:

a phacoemulsification handpiece having a needle, the needle configured to be ultrasonically vibrated;

a power source configured to provide pulsed electrical power to the handpiece; and

a computer programmed to control the power source such that the pulsed electrical power to the handpiece has a pulse repetition rate in a range greater than 25 pulses per second and less than 2000 pulses per second.

2. **(Previously Presented)** The lens extraction apparatus according to claim 22, wherein said switch comprises a footswitch.

3. (Cancelled)

4. **(Previously Presented)** The lens extraction apparatus according to claim 22, wherein said switch enables a linear selection of the ultrasonic pulse amplitude.

5. **(Previously Presented)** The lens extraction apparatus of claim 2, wherein continued linear footswitch displacement enables activation of a series of pulse duty cycles of power supplied to the handpiece.

6. **(Currently Amended)** A phacoemulsification apparatus comprising: a phacoemulsification handpiece having

a needle, the needle configured to be ultrasonically vibrated;

a power source configured to provide pulsed electrical power to the handpiece;

an input enabling a surgeon to select ~~at least one of~~ an ultrasonic pulse amplitude and a pulse duty cycle supplied to the handpiece; and

a computer programmed to respond to the selected pulse amplitude [[or]] and the selected pulse duty cycle, the computer further programmed to control the power source such that the pulsed electrical power has an off duty cycle to ensure heat dissipation before a subsequent pulse is activated.

7. **(Previously Presented)** The phacoemulsification apparatus according to claim 6, wherein said input comprises a switch.

8. **(Previously Presented)** The phacoemulsification apparatus according to claim 6, wherein said computer controls the power source to provide pulsed electrical power with a pulse repetition rate of between about 25 and about 2000 pulses per second.

9. **(Previously Presented)** The phacoemulsification apparatus according to claim 6, wherein said input enables a linear selection of pulse amplitude.

10. **(Canceled)**

11. **(Canceled)**

12. **(Canceled)**

13. **(Canceled)**

14. **(Currently Amended)** A method for operating a phacoemulsification system, the system including a phacoemulsification handpiece, a power source configured to provide pulsed electrical power to the handpiece, and a control unit, said method comprising:

(a) providing pulsed electrical power from the power source to the handpiece for performing the phacoemulsification procedure;

([[f]]b) controlling the power provided to the handpiece to have a pulse repetition rate in a range greater than 25 pulses per second and less than 2000 pulses per second.

15. **(Canceled)**

16. **(Currently Amended)** The method according to claim 14, wherein controlling [[the]] the power provided to the handpiece includes controlling a pulse duty cycle in a linear manner.

17. **(Previously Presented)** The method according to claim 16, wherein controlling a pulse duty cycle includes the use of a footswitch which angles in at least one ordinal plane.

18. **(Previously Presented)** The method according to claim 14, further including controlling an amplitude of power pulses via a footswitch.

19. **(Canceled)**

20. **(Currently Amended)** The method of claim 14, further comprising the provision of a second instrument for a bimanual phacoemulsification procedure.

21. **(Currently Amended)** The method of claim 14, ~~whereby the heat resulting in tissue insult is mitigated providing a clear cornea within the first post-operative day.~~ wherein the pulsed electrical power includes off duty cycles between pulses, and further wherein the method further comprises controlling the off duty cycles to ensure heat dissipation before a subsequent pulse is actuated.

22. **(Previously Presented)** The lens extraction apparatus according to claim 1, further including a switch configured to receive manual input of at least one of an ultrasonic pulse amplitude and a pulse duty cycle.

23. **(Previously Presented)** The phacoemulsification apparatus according to claim 7, wherein said switch comprises a footswitch, the footswitch configured to enable a surgeon to linearly control the pulse duty cycle.

24. **(Previously Presented)** The method according to claim 14, wherein controlling the power provided to the handpiece includes controlling a pulse duty cycle

REMARKS

As an initial matter, the Applicants would like to thank the Examiner for taking the time to meet with the Applicants' attorney on June 21, 2006, and also for his ongoing efforts to work with the Applicants on the present application.

The Specification

Paragraph [0087] has been replaced with a new paragraph in accordance with the examiner's comments in para. 3 of the Examiner's Official Action dated April 18, 2006 ("Official Action"). The Applicants appreciate the correction.

The Claims

Claims 1, 2, 4-9, 14, 16-18 and 20-21 are currently pending in the present application, of which claims 1, 6, and 14 are independent. Claims 6, 14, 16, 20, and 21 have been amended to correct typographical errors and/or to improve clarity. New language in claim 21 is taken from original claim 14. No new subject matter has been added.

Claim Objections

Claims 16 and 20 have been amended to correct the typographical errors noted by the Examiner in paras. 4 and 5 of the Official Action respectively. Claim 14 has been amended to correct a typographical error as well. Claim 21 has been amended to remove the language that the Examiner objected to in paragraph 6 of the Official Action.

112 Rejection

The examiner rejected claim 20 under 35 U.S.C. § 112, 1st paragraph, as failing to comply with the enablement requirement. In response, the Applicants respectfully note that "satisfactory description may be in the claims or any other portion of the originally filed specification." *See* MPEP § 2163 § 1, *see also In re Koller*, 613 F.2d 819, 204 USPQ 702 (CCPA 1980) (original claims constitute their own description); *accord In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); *accord In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976).

The language of current claim 20 is taken from originally filed claim 19, which includes the following language: "provision of a second instrument, or a bimanual phacoemulsification probe." Accordingly, the Applicants respectfully traverse the Examiner's rejection under 35 U.S.C. § 112.

102 Rejections

The examiner rejected claims 6, 7, 9, and 23 under 35 U.S.C. § 102(b) as being anticipated by Williams, Jr. *et al.* ('503) ("Williams"). The Applicants amended claim 6 per the Examiner's suggestion and therefore believe that claim 6, as currently amended, answers the Examiner's rejections under 35 U.S.C. § 102(b). Additionally, the Applicants respectfully traverse these rejections because Williams fails to disclose, teach or suggest a phacoemulsification apparatus having a computer "programmed to control the power source such that the pulsed electrical power has an off duty cycle to ensure heat dissipation before a subsequent pulse is activated" as required by claims 6, 7, 9, and 23. The present application uses an off-duty cycle to prevent tissue de-compensation caused by the heat of the ultrasound power while still maintaining an effective power level. *See, e.g.,* para. [0065]. While Williams does disclose the use of a "pulsating mode" to allow the irrigation/aspiration functions to periodically clear the eye of material during a surgical procedure using phacoemulsification (col. 14, ll. 47-50), Williams does not disclose, teach, or suggest the use of an off-duty cycle to dissipate heat and prevent tissue de-compensation. In fact, Williams actually teaches away from the claimed invention by stating that the "pulse rate control [in the Williams system] is NOT used to adjust the desired phacoemulsification power level." (col. 14, ll. 43-45)(emphasis added). Accordingly, the Applicants respectfully submits that independent claim 6, and its dependent claims, 7, 9, and 23 are patentable over the cited art.

103 Rejections

The examiner rejected claims 1, 2, 4, 5, and 22 under 35 U.S.C. § 103 as being obvious over Williams and further rejected claims 14, 16-18, and 24 as being obvious over Williams in view of Ludin *et al.* ('683) ("Ludin"). The Applicants respectfully traverse because, as the Examiner admits in the Office Action, none of the cited references discloses, teaches, or suggests providing power to a phacoemulsification handpiece at a pulse repetition rate within the range of 25 to 2000 pulses per second. As described in the specification, one objective of the present invention is to minimize tissue de-compensation caused by the heat of the phacoemulsification needle while still maintaining an effective power level. Para. [0065]. One approach described in the specification to address this objective is to provide the power in pulses coupled with off-duty cycles at a pulse repetition rate greater than 25 pulses per second. This is neither taught, disclosed, nor suggested in the cited art or combinations thereof, and it is not a simple design choice or obvious variation. *See* MPEP 2141 § II(c)("The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention); 2142 ("The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness"). In fact, Williams actually teaches away from the claimed invention by stating that the "pulse rate control [in the Williams system] is NOT used to adjust the desired phacoemulsification power level." (col. 14, ll. 43-45)(emphasis added). Instead, Williams teaches using pulse rate control to allow the irrigation/aspiration functions to periodically clear the eye of material during operation. (Col. 14, ll. 45-47). As for Ludin, Ludin teaches varying the power level provided to the ultrasonic handpiece in response to the temperature of the ultrasonic needle (Ludin, col. 3, ll. 9-11); however, no where in Ludin is there taught, disclosed, or suggested a phaco system that adjusts the pulse rate to within the range of 25 to 2000 pulses per second. Accordingly, the Applicants respectfully submit that independent claims 1 and 14 and their respective dependent claims 2, 4, 5, 22, 16-28, and 24 are patentable over the cited art.

CONCLUSION

In view of the foregoing, it is respectfully submitted that all claims of the present application are in condition for allowance. Reconsideration and allowance of all pending claims at an early date is respectfully requested.

Applicants believe that no fees are due in accordance with this Amendment beyond those included herewith. Should any additional fees be due, the Commissioner is hereby authorized to charge any deficiencies or credit any overpayment to Deposit Account 502317.

Respectfully submitted,

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